

Safety of optical coherence tomography in daily practice: a comparison with intravascular ultrasound

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Aims

Previous studies have reported the safety and feasibility of both time-domain optical coherence tomography (TD-OCT) and Fourier-domain OCT (FD-OCT) in highly selected patients and clinical settings. However, the generalizability of these data is limited, and data in unselected patient populations reflecting a routine cathlab practice are lacking. We compared safety of intracoronary FD-OCT imaging to intravascular ultrasound (IVUS) imaging in a large real-world series of consecutive patients who underwent invasive imaging during coronary catheterization in our centre.

Methods and results

This is a prospective, single-centre registry of patients scheduled for coronary angiography or intervention undergoing intracoronary imaging with FD-OCT or IVUS between April 2008 and December 2013. Intra-procedural and major in-hospital adverse events that could be possibly related to invasive imaging were registered routinely by the operator as part of our clinical report and prospectively recorded in our database. These events were retrospectively individually adjudicated by an independent safety committee. Between April 2008 and December 2013, 13 418 diagnostic or interventional coronary catheterization procedures were performed. Of these, 1142 procedures used OCT and 2476 procedures used IVUS. Invasive imaging-related complications were rare, did not differ between the two imaging methods (OCT: $n = 7$, 0.6%; IVUS: $n = 12$, 0.5%; $P = 0.6$), and were self-limiting after retrieval of the imaging catheter or easily treatable in the catheterization laboratory. No major adverse events, prolongation of hospital stay, or permanent patient harm was observed.

Conclusion

FD-OCT is safe in an unselected and heterogeneous group of patients with varying clinical settings.

Keywords

Optical coherence tomography • Intravascular ultrasound • Safety • Adverse events

Introduction

Intracoronary optical coherence tomography (OCT) is increasingly used in the catheterization laboratory. Various clinical applications have been proposed, including assessment of plaque morphology in angiographic ambiguous lesions, guidance of stent placement during percutaneous coronary interventions (PCI), and follow-up stent assessment.^{1,2} In the early days of the first generation, time-domain OCT (TD-OCT), intracoronary application was hampered

by the need for proximal balloon occlusion to limit antegrade blood flow in combination with distal delivery of a translucent flush solution in order to create a blood-free environment during OCT data acquisition.³ The currently commercially available and widespread used second-generation intracoronary Fourier-domain OCT (FD-OCT) was developed to overcome these limitations, allowing for a simplification of the image acquisition procedure. Importantly, the imaging device was redesigned to a monorail OCT imaging catheter that could be introduced into the coronary artery over any PCI

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guide wire of choice, which substantially facilitated instrumentation. Further, the data acquisition speed was increased by using frequency domain techniques that are capable of acquiring images at high speed (up to 180 frames/s) and with fast pullback (up to 40 mm/s), alleviating the need for proximal balloon occlusion during imaging and the risk of creating ischaemia during imaging.⁴ Previous smaller studies^{5–10} have reported the safety and feasibility of both TD-OCT and FD-OCT in highly selected patients and clinical settings. However, the generalizability of these data is limited, and data in unselected patient populations reflecting a routine cathlab practice are lacking.

We report safety of intracoronary FD-OCT imaging in a large real-world series of consecutive patients who underwent OCT during coronary catheterization in our centre since the introduction of FD-OCT imaging in 2008 and compare the results with our intravascular ultrasound (IVUS) safety data from the same time period.

Methods

Study population

This is a single-centre study, prospectively evaluating the safety of FD-OCT. Consecutive patients who underwent FD-OCT examination during cardiac catheterization between April 2008 and December 2013 were included. These data were then compared with the cohort of patients who underwent IVUS within the same time period. All consecutive patients who underwent intracoronary OCT or IVUS during the study period were included. Additionally, to assess generalizability of our data, the indications for catheterization and patient baseline characteristics were also compared with the cohort that, at the discretion of the operators, did not undergo any form of invasive imaging during the same time period. Both OCT and IVUS were performed either as part of various clinical trial protocols or at the discretion of the operators. In the latter case, the exclusion criteria were acute, life-threatening haemodynamic instability and coronary anatomy not deemed suitable for introduction of an imaging catheter, such as extensive tortuosity or calcification or a lumen diameter >5 mm, beyond the penetration depth of OCT and lesions considered too tight to allow crossing of a device of ~3F. In acute settings, restoration of antegrade flow always was the main priority and had to be secured before introduction of an imaging catheter.

Invasive imaging procedure

Invasive imaging was performed via radial or femoral access according to routine clinical standard in our centre using 6F (range 5–7F) guide catheters. Patients received weight-adjusted intravenous heparin in order to maintain the activated clotting time of >300 s and intracoronary administration of 0.2 mg nitroglycerine, as standard prior to invasive imaging. Imaging catheters were advanced distally to a region of interest over 0.014-inch conventional angioplasty guide wires, chosen at the discretion of the operators. All the imaging systems have dedicated pullback devices and consoles that allow data processing and storage.

IVUS image acquisition

IVUS images were acquired with different systems (Galaxy I, Galaxy II and iLab: Boston Scientific, Marlborough, MA, USA; In-Vision Gold and S5 imaging system: Volcano Corporation, San Diego, CA, USA). Different types of catheters (range 20–45 MHz, 3.2–3.5F) were used with a default motorized pullback speed of 0.5 mm/s.

OCT image acquisition

OCT imaging was performed with commercially available FD-OCT systems (Lightlab C7XR, Ilumien and Ilumien Optis: St Jude Medical, St Paul, MN, USA; Terumo Lunawave: Terumo, Tokyo, Japan) and in a limited number of patients with several different OCT prototypes (Lightlab M4: St Jude Medical, St Paul, MN, USA; MGH OCT system: The Wellman Center for Photomedicine, Boston, MA, USA; Volcano OCT system: Volcano Corporation, San Diego, CA, USA).

OCT imaging probes had a short monorail design with a fibre-optic imaging core integrated into a catheter. The catheter profile ranged from 2.4 to 2.7F. During OCT image acquisition, the optic imaging core rotated at a rate of 100–180 revolutions/s. OCT pullbacks were performed automated at the pullback speed of generally 20 mm/s (range 10–40 mm/s) during simultaneous flushing of viscous iso-osmolar contrast (Iodixanol 320, Visipaque™, GE Health Care, Cork, Ireland at 37°C) through the guiding catheter by use of an automated power injector (Medrad Inc., Warrendale, PA, USA) with a flow rate of 3 mL/s as standard setting, or in selected cases by manual injection.

Safety assessment

Both major in-hospital and intra-procedural adverse events were recorded and considered as potential imaging-related complications. Major in-hospital adverse events were defined as cerebrovascular event, emergency revascularization, and death. Intra-procedural events were defined as the occurrence of clinical symptoms (new or worsened chest pain or shortness of breath), adverse angiographic outcomes (dissection, perforation, vasospasm, thrombus formation, and no-reflow), or electrocardiographic changes (ST-segment elevation, severe bradycardia, and ventricular arrhythmias) requiring interruption of the imaging procedure during intracoronary imaging and were routinely registered by the operator as a standard item being part of our clinical PCI report and collected in our PCI database. In addition, all free text comments in the PCI database/reporting system were screened for 'OCT' or 'IVUS'. Comments containing these keywords were individually reviewed for any possible association with an adverse event. Major peri-procedural adverse events were also recorded and defined as cerebrovascular event, emergency revascularization, and death.

Adjudication

Complications were individually adjudicated by an independent safety committee by thorough review of the patient files, procedural notes, angiogram, and intracoronary images. A complication was considered related to the imaging procedure if it would not have occurred if the invasive imaging would not have been performed. 'Definitely related' was used for complications that were with great certainty caused by the invasive imaging. If the relation between invasive imaging procedure and registered event was less clear, but could not be completely ruled out, the event was defined as 'possibly related'. Possible and definite invasive imaging-related events were categorized as self-limiting after withdrawal of the imaging catheter, requiring action or major adverse events. The safety committee consisted of two teams that reviewed the events independently. In case of disagreement, the case was re-evaluated and discussed between both teams until consensus was reached. Each team consisted of a senior invasive cardiologist not directly involved in clinical or research coronary imaging projects and an invasive imaging expert (R.J.G. and J.M.R.L.; M.V. and K.T.W.).

Statistical analysis

Continuous data were expressed as mean values \pm SD. An independent-samples t-test was used to analyse continuous data between two groups and ANOVA for more than two groups. Significance

of associations of categorical variables were assessed using the χ^2 test or Fisher's exact test, as appropriate. Univariate analyses to identify predictors of an adverse event during image acquisition were performed using a logistic regression model. A *P*-value of <0.05 was considered significant.

Results

Patient population

Between April 2008 and December 2013, 13 418 diagnostic or interventional coronary catheterization procedures were performed in our centre. During 1142 procedures (984 patients with 3045 pullbacks) FD-OCT was used, and during 2476 procedures (2054 patients with 5148 pullbacks) IVUS was used. A combination of OCT and IVUS images were acquired during 307 procedures. Invasive imaging was performed by 13 different senior operators, of whom 11 had >5 years of experience and the other two between 1 and 5 years of experience as senior operator in a catheterization laboratory. Baseline demographic characteristics of all patients who underwent OCT or IVUS are displayed in Table 1. Invasive imaging was used in a variety of clinical settings. Patients undergoing OCT had less renal failure (5.3 vs. 9.1%, $P < 0.001$) when compared with IVUS. OCT imaging was performed more often in patients with ST-elevation myocardial infarction (24.7 vs. 14.5%, $P < 0.001$). Procedural characteristics are given in Table 2. The mean number of pullbacks per procedure was significantly higher in the OCT group compared with IVUS (2.66 vs. 2.07, $P < 0.001$), which might be explained in part by the shorter artery segment, which can be visualized in one pullback (typically 50 mm OCT vs. 100 mm IVUS). Imaged vessels and lesion types were roughly equal. Clearing of the coronary from blood during OCT imaging was performed with a contrast flush rate of 3 mL/s in 78% and 4 mL/s in 21% of the pullbacks.

Generalizability of invasive imaging cohorts

Table 3 shows the comparison of baseline characteristics of the OCT and IVUS cohorts to the population that did not undergo invasive imaging within the same time window. The most pronounced differences were the higher incidence of renal failure (12.7 vs. 5.3 vs. 9.1%, $P < 0.001$) in the non-imaging group, the lower incidence of patients with a prior PCI (26.9 vs. 46.4 vs. 42.7%), and the larger number of type C lesions (35.9 vs. 25.2 vs. 24.1%, $P < 0.001$) when compared with OCT and IVUS, respectively. Figure 1 illustrates three examples of clinical settings that are typically considered difficult for invasive imaging acquisition. OCT images were successfully acquired in all of these cases without complications.

Safety assessment

After adjudication, 7 (0.6%) complications that occurred during image acquisition were possibly or definitely related to OCT and 12 (0.5%) to IVUS imaging ($P = 0.6$) (Figure 2). Table 4 further specifies the complications as adjudicated. Transient ST-elevation requiring withdrawal of the imaging catheter was seen in 0.26 vs. 0.08% ($P = 0.2$), hypotension during image acquisition in 0.18 vs. 0.04% ($P = 0.2$), coronary spasm requiring infusion of additional intracoronary nitroglycerin in 0.09 vs. 0.04% ($P = 0.6$), thrombus formation

Table 1 Characteristics of all consecutive patients undergoing invasive imaging in our centre between 2008 and 2013

| Procedures | OCT ^a | IVUS ^a | P-value |
|---------------------------------|------------------|-------------------|----------|
| <i>n</i> | 1142 | 2476 | |
| Age, years | 61.9 \pm 11.1 | 62.6 \pm 11.2 | 0.112 |
| Male | 853 (74.7) | 1852 (74.8) | 0.967 |
| Risk factors | | | |
| Hypertension | 589 (53.9) | 1465 (62.0) | <0.001 |
| Diabetes | 206 (18.1) | 500 (20.5) | 0.105 |
| Dyslipidaemia | 600 (55.3) | 1413 (60.4) | 0.006 |
| Current smokers | 299 (26.3) | 576 (23.5) | 0.073 |
| Family history | 471 (44.0) | 1025 (44.2) | 0.911 |
| History | | | |
| Prior myocardial infarction | 344 (30.1) | 776 (31.3) | 0.462 |
| Prior CABG | 50 (4.4) | 136 (5.5) | 0.169 |
| Prior PCI | 529 (46.3) | 1058 (42.7) | 0.047 |
| Renal Failure | 60 (5.3) | 224 (9.1) | <0.001 |
| Indications for catheterization | | | <0.001 |
| Stable angina | 433 (37.9) | 1114 (45.0) | <0.001 |
| Unstable angina | 180 (15.7) | 466 (18.8) | 0.028 |
| Non-STEMI | 97 (8.5) | 233 (9.4) | 0.385 |
| STEMI | 282 (24.7) | 360 (14.5) | <0.001 |
| Other | 150 (13.1) | 303 (12.2) | 0.45 |

^aA combination of OCT and IVUS images were acquired during 307 procedures. Age: mean \pm standard deviation; other values: *n* (%).

Table 2 Invasive imaging procedure details

| Procedures | OCT | IVUS | P-value |
|-------------------------------------|-----------------|-----------------|----------|
| <i>n</i> | 1142 | 2476 | |
| Mean number of pullbacks | 2.66 \pm 1.54 | 2.07 \pm 1.32 | <0.001 |
| Mean number of imaged vessels | 1.18 \pm 0.42 | 1.28 \pm 0.51 | <0.001 |
| Total pullbacks, <i>n</i> | 3042 | 5135 | |
| Pullback distribution among vessels | | | <0.001 |
| LAD | 1484 (48.8) | 2459 (47.9) | 0.436 |
| LCX | 577 (19.0) | 1136 (22.1) | 0.001 |
| RCA | 846 (27.8) | 1266 (24.7) | 0.002 |
| Other | 135 (4.4) | 274 (5.3) | 0.074 |
| Lesion type, <i>n</i> | 946 | 1927 | 0.584 |
| A | 115 (12.2) | 214 (11.1) | 0.418 |
| B1 | 235 (24.8) | 519 (26.9) | 0.241 |
| B2 | 358 (37.8) | 729 (37.8) | 1.000 |
| C | 238 (25.2) | 465 (24.1) | 0.549 |

Values in *n* (%) or mean (\pm standard deviation).

in 0.09 vs. 0.16% ($P = 0.6$), dissection of the imaged vessel in 0.00 vs. 0.12% ($P = 0.2$), and stent deformation in 0.00 vs. 0.04% ($P = 0.5$) during OCT and IVUS imaging, respectively. The event rate per

Table 3 Comparison between invasive imaging cohorts and non-imaging population

| | OCT | IVUS | Non-imaging | P-value |
|---------------------------------|-------------|-------------|-------------|---------|
| N | 1142 | 2476 | 10 107 | |
| Age, years | 61.9 ± 11.1 | 62.6 ± 11.2 | 63.7 ± 12.8 | <0.001 |
| Male | 853 (74.7) | 1852 (74.8) | 6992 (69.2) | <0.001 |
| Risk factors | | | | |
| Hypertension | 589 (53.9) | 1465 (62.0) | 5037 (54.6) | <0.001 |
| Diabetes | 206 (18.1) | 500 (20.5) | 1981 (20.3) | 0.210 |
| Dyslipidaemia | 600 (55.3) | 1413 (60.4) | 4347 (48.0) | <0.001 |
| Current smokers | 299 (26.3) | 576 (23.5) | 2345 (24.1) | 0.180 |
| Family history | 471 (44.0) | 1025 (44.2) | 3248 (36.6) | <0.001 |
| History | | | | |
| Prior myocardial infarction | 344 (30.1) | 776 (31.3) | 2324 (23.4) | <0.001 |
| Prior CABG | 50 (4.4) | 136 (5.5) | 1002 (10.1) | <0.001 |
| Prior PCI | 529 (46.3) | 1058 (42.7) | 2682 (26.9) | <0.001 |
| Renal Failure | 60 (5.3) | 224 (9.1) | 1260 (12.7) | <0.001 |
| Indications for catheterization | | | | <0.001 |
| Stable angina | 433 (37.9) | 1114 (45.0) | 2768 (27.4) | <0.001 |
| Unstable angina | 180 (15.7) | 466 (18.8) | 1552 (15.4) | <0.001 |
| Non-STEMI | 97 (8.5) | 233 (9.4) | 1271 (12.6) | <0.001 |
| STEMI | 282 (24.7) | 360 (14.5) | 2787 (27.6) | <0.001 |
| Other | 150 (13.1) | 303 (12.2) | 1729 (17.1) | <0.001 |
| Lesion type, n | 946 | 1927 | 7263 | <0.001 |
| A | 115 (12.2) | 214 (11.1) | 571 (7.9) | <0.001 |
| B1 | 235 (24.8) | 519 (26.9) | 1690 (23.3) | 0.003 |
| B2 | 358 (37.8) | 729 (37.8) | 2398 (33.0) | <0.001 |
| C | 238 (25.2) | 465 (24.1) | 2604 (35.9) | <0.001 |

pullback was the same for both modalities (0.23%). *Figure 3* shows an example of a typical angiographic and OCT image of coronary spasm occurring during image acquisition. A more detailed description of all the complications that were encountered can be found in the Supplementary data online.

Risk factors for adverse event

All baseline characteristics and indications for catheterization were tested in univariate analyses for the risk of invasive imaging events (see Supplementary data online, *Table S1*). The use of both modalities, the total number of pullbacks, and the total number of invasively imaged main vessels were also tested. No predictor of adverse events was identified in the individual OCT and IVUS cohorts, nor in the combined invasive imaging cohort. Additionally, the impact of the interventional cardiologist's experience with the use of invasive imaging on the risk of an adverse events was evaluated. When compared with the most experienced operator, there was no significant increase in risk for every individual senior operator.

Discussion

The present study demonstrates that intracoronary OCT and IVUS imaging is comparably safe in an unselected and heterogeneous

group of patients with varying clinical settings, reflecting daily routine catheterization laboratory practice in a tertiary care centre. Imaging-related events were scarce, with a similar incidence for OCT and IVUS imaging and most importantly, self-limiting after withdrawal of the imaging catheter or easily treatable in the catheterization laboratory. No major adverse events, prolongation of hospital stay, or permanent patient harm was observed.

Comparison between the OCT and IVUS cohorts

During the study period, the frequency in the use of OCT and IVUS has changed in our centre. In 2008, OCT was not yet CE marked and, thus, infrequently used. In 2013, however, the use of OCT and IVUS has balanced out (*Figure 4*). While IVUS was more often performed in patients with stable angina, OCT was used more often in ST-segment elevation myocardial infarction (STEMI) patients. OCT has a higher sensitivity in visualizing thrombus and plaque ruptures, often present in STEMI patients.

OCT and IVUS were used in a heterogeneous population and in several clinical settings. Although most non-imaging variables in *Table 3* differ significantly from the OCT and IVUS cohorts, most differences can be explained by the features that are inextricably linked to both modalities. For example, in patients with renal failure, X-ray

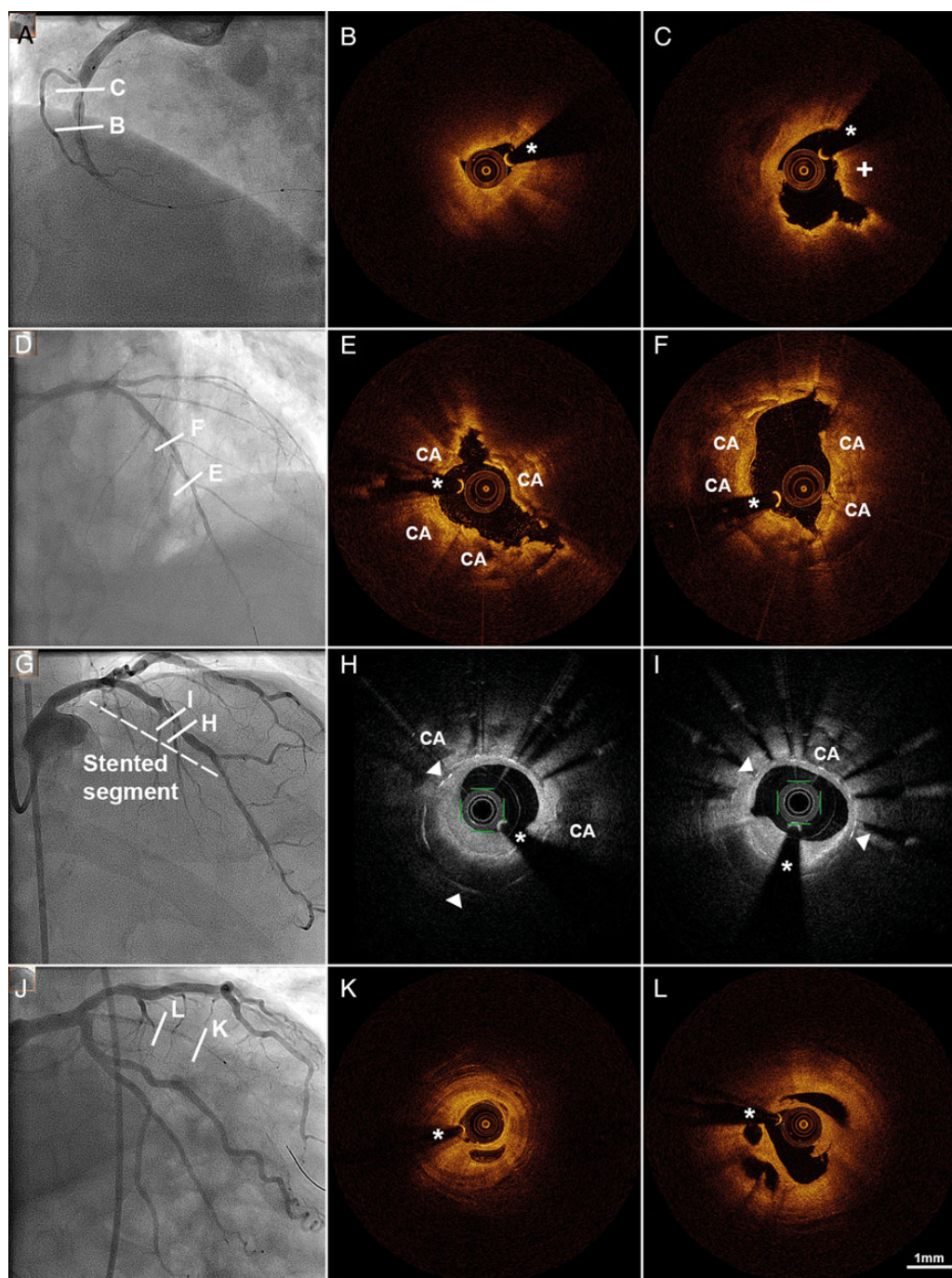


Figure 1 Examples of the use of OCT in different clinical settings. Angiogram (A) of a STEMI patient with corresponding OCT cross-sectional images (B and C) with the presence of thrombus (+). Angiogram (D) of a severely calcified vessel, which is clearly appreciated (CA) on the OCT images (E and F) after lesion preparation with a cutting balloon and rotablator. Angiogram (G) of a patient with in-stent restenosis. The OCT images reveal a lesion with neointimal hyperplasia within the stent (H and I). Angiographic (J) and OCT image acquisition (K and L) in a recanalized chronic total occlusion. *Guide wire artefact.

contrast exposure has to be kept to a minimum. This explains the smaller numbers of patients with renal impairment in the OCT and, in lesser extent, the IVUS group. In patients with a chronic total occlusion (lesion type C), operators are less inclined to use invasive

imaging, while additional imaging can be of great help in complex lesions (type B2), such as bifurcations. We believe that our data reflect the diversity in the use of invasive imaging and its many possible applications.

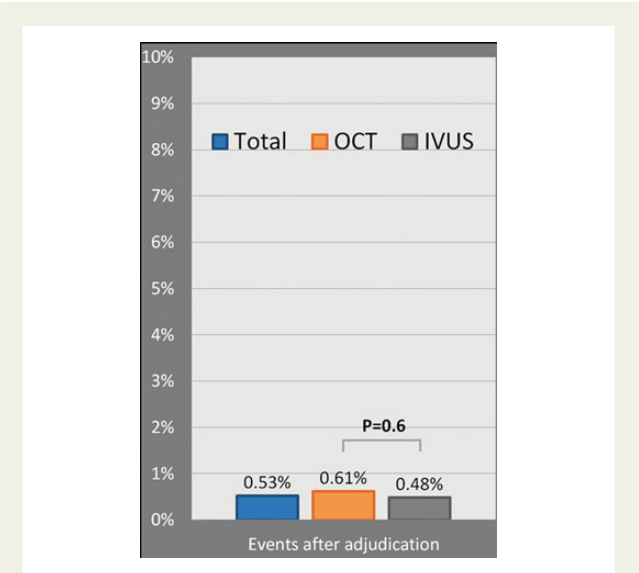


Figure 2 Event rates of IVUS and OCT after adjudication.

Table 4 Invasive imaging complications after adjudication

| | OCT | IVUS | P-value |
|------------------------|----------|----------|---------|
| Transient ST-elevation | 3 (0.26) | 2 (0.08) | 0.2 |
| Bradycardia | 2 (0.18) | 1 (0.04) | 0.2 |
| Coronary spasm | 1 (0.09) | 1 (0.04) | 0.6 |
| Thrombus formation | 1 (0.09) | 4 (0.16) | 0.6 |
| Dissection | 0 (0.00) | 3 (0.12) | 0.2 |
| Stent deformation | 0 (0.00) | 1 (0.04) | 0.5 |
| Major adverse events | 0 (0.00) | 0 (0.00) | NA |

Values in n (%).

Previous studies demonstrating the safety of OCT

OCT’s need of clearance of blood from the vessel during image acquisition was perceived as the Achilles heel in the early days of intracoronary OCT imaging with time-domain technology, limiting its clinical application to a few expert centres. Today, this problem is largely solved by the introduction of FD-OCT technology. With FD-OCT, the need to clear the artery temporarily from blood does not appear as a major drawback anymore. The first studies that reported the safety of OCT^{10,11} used the currently abandoned TD-OCT systems. At that time, OCT image acquisition was relatively slow (frame rate 15 frames/s and pullback speed of 1 mm/s) and thus requiring longer pullback times with temporary occlusion of the proximal vessel segment using a dedicated occlusion balloon. Prati et al.⁵ were the first to perform OCT with a pullback speed of 3 mm/s and a non-occlusive technique demonstrating improved feasibility and reduced complication risk. This was then confirmed in a larger multicentre registry⁶ comparing the occlusive balloon technique (n = 256) to the non-occlusive TD-OCT (n = 212)

technique. No major adverse cardiac events (MACE) were observed during or in the 24 h period following OCT imaging.

The first study to report the safety and feasibility of FD-OCT was published by Imola et al.⁷ in a group of 90 patients with unstable or stable coronary artery disease. In this population, one case of coronary spasm was recorded, but no MACE were observed. Likewise, two other studies^{8,9} reported FD-OCT safety in small, selected groups. Our study presents safety of OCT in a high-volume centre, over several years. The findings corroborate the results of the prior, smaller studies with complication rates of 0–2%. The few complications that were encountered were all resolved before the patient left the catheterization laboratory. These complications were also in line with individual case reports that described rare adverse events during OCT imaging.^{12–15} Importantly, our large-scale, systematic registry can demonstrate that these complications occur very rarely (all <0.2%) in a tertiary, high-volume centre and seem to happen randomly.

Comparison with IVUS

Although IVUS image acquisition shows many similarities to that of OCT, there are some distinct differences, most importantly IVUS’s lack of need for a temporarily blood-free environment. Despite the differences, complications are seen very rarely for both modalities and do not significantly differ. In our study, we report 12 (0.5%) adverse events during IVUS image acquisition.

Large IVUS safety trials have been performed,^{16,17} reporting 1–3% complications, a number that may be partially driven by a larger catheter size. The most recent large-scale study implementing IVUS, the PROSPECT¹⁸ study, reported 11 patients (1.6%) with complications that were attributed to IVUS procedures. In contrast to our findings, all events were caused by mechanical damage (10 dissections and 1 perforation) to the vessel wall. The reasons for this difference is unclear. The mean number of vessels that were imaged with IVUS in our cohort is 1.28 per procedure, in contrast to the three vessels that were imaged as part of the protocol in the PROSPECT study. Furthermore, in the PROSPECT study, images were acquired within a shorter time window and in multiple centres.

Risk factors for adverse event

We did not find any patient characteristics, nor any procedural-related characteristics that increase the chance of occurrence of an imaging-related event in the light of our very low event rate. The absence of risk factors most likely demonstrates that adverse events occur infrequently and randomly, implicating that OCT and IVUS can both be used in a large variety of patients and in different clinical settings. We additionally explored if the amount of adverse events declined with increasing experience; however, an association between the operator’s experience and the number of imaging procedures was not identified, tracking with previous reports.⁹

Limitations

A limitation of this study is its design. Collection of data has been recorded over several years as part of our clinical routine catheterization database. This could possibly cause inconsistency and create bias. Furthermore, reproduction of the procedures associated with adverse events that occurred during coronary catheterizations that were performed years ago can be complex. However, the

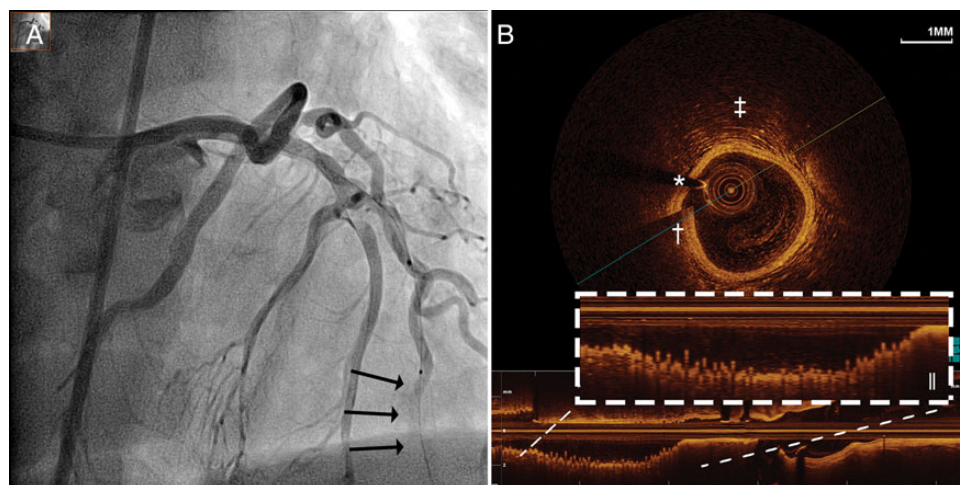


Figure 3 Coronary spasm during OCT pullback. Angiogram (A) and OCT image (B) of a diagonal branch with coronary spasm. Vasospasm can potentially mimic streaming effect due to poor contrast injection or dissection on the coronary angiogram. The seam-line (†) and non-uniform rotational distortion artefact (‡) on the cross-sectional and the 'sawtooth' appearance (||) on the longitudinal image, together with poor clearing of the artery from blood (arrows) despite good guide catheter position, suggest that coronary spasm could be present. *Guide wire artefact.

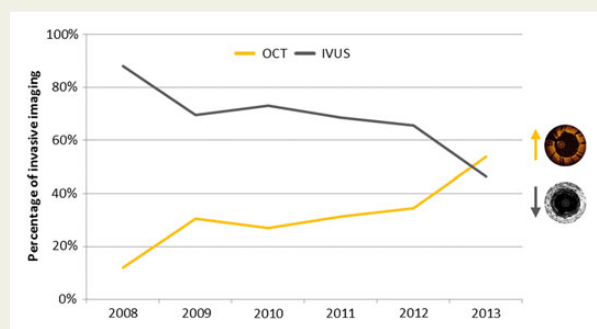


Figure 4 Change of invasive imaging policy during the study period. The use of IVUS and OCT has balanced out over time.

registration of events is done by experienced operators in a standardized way and for a long period of time. We included every patient undergoing FD-OCT and IVUS within the selected time window and used all available procedural data to reproduce the procedures with two independent adjudication committees. Therefore, we feel that the reported results represent clinical practice. The fact that imaging was acquired at the discretion of very experienced operators could create selection bias. Moreover, the high level of experience in this single-centre study does not mean that reported results can be translated to less experienced centres. Furthermore, it is of note that it is possible that the differences in clinical characteristics between OCT, IVUS, and non-imaging groups as presented in Table 3 were mainly driven by its use in predefined research protocols in specific clinical settings. However, we intentionally included all imaging procedures that have taken place within the specified time window to assure that the presented data represent a modern, real-world catheterization laboratory population. Success rates of individual pullbacks were not routinely recorded in our databases.

Therefore, we were unable to report on the feasibility of OCT image acquisition in daily clinical practice.

Another limitation of this study is that we were not able to report the incidence of peri-procedural myocardial infarctions and contrast-induced nephropathy, as the majority of our patients are being transferred to the referring hospital within 6 h after the procedure or dismissed after an uneventful procedure.

Conclusion

FD-OCT is safe in an unselected and heterogeneous group of patients with varying clinical settings. Adverse events that occur during image acquisition are rare, and similar to the event rates occurring during IVUS image acquisition.

Supplementary data

Supplementary data are available at *European Heart Journal – Cardiovascular Imaging* online.

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